Comments for SACHRP prisoner panel

My name is Gary L. Chadwick, PharmD, MPH, CIP. I am an Associate Provost and Director of the University of Rochester's Office for Human Subject Protection and Associate Professor of Medical Humanities in the School of Medicine and Dentistry. In the past have been involved in the regulation process both within Office for Protection from Research Risks (OPRR) and the Food and Drug Administration. I am here today to provide my comments about the interpretation made by the OPRR/Office for Human Research Protection on the human subject protection regulations for prisoners.

I disagree with the current interpretation. The new interpretation, which dates from the spring of 2000, requires that subpart C be applied whenever any human subject in a research protocol governed by 45 CFR 46 becomes incarcerated. A common example is an AIDS trial that has enrolled a competent adult subject, who subsequently becomes incarcerated. Under the current guidance, the IRB must review the protocol again with a prisoner representative in attendance and make the special determinations for a prisoner study. I don't see the utility in doing this.

The requirement to re-review these studies simply because a previously enrolled subject becomes incarcerated is not practical and does not provide either this subject or others in the study any greater level of protection, and, in an era in which we are trying to decrease burden on IRBs, this requirement adds unnecessary burden to IRBs, distracts the investigator and confuses the subject. This interpretation over-turns a 20-year policy that was working well for studies conducted outside of the prison setting.

Under the regulations at 46.305(a)(1-7), the IRB must make seven special determinations over and above those made when approving studies under the general protections of subpart A. These seven findings make sense for studies that are conducted in prison settings. Making these determinations in a general-population study in order to include subjects who become incarcerated after enrollment does not make sense. For example, the first finding asks that the activity be categorized for its application to studies in prisons. In many cases, this is not appropriate; sometimes it is impossible; and sometimes it would require the study be stopped until a special panel could be held. The findings required by (2) and (3) are automatic because non-prisoners are already enrolled. Finding (4) is not applicable because no selection is made from prison populations. Finding (5) again is not applicable because the subject has already read the consent form and participated in the consent process and agreed to enroll in the study. Reviewing language of the consent form at this point seems superfluous. How does finding (6) – lack of affect on parole boards – apply to someone who was able to, and did, give voluntary consent before incarceration? This finding is particularly problematic for many AIDS studies because the NIH Division of AIDS has given guidance that only a written agreement between the research institution and the jail/prison satisfies them that this finding is met. This adds delay and burden. It is not unusual that subjects receiving treatment through open-label studies are dropped from studies and lose their access to care because of the effect of this over-stretched interpretation. This is truly unfortunate, especially considering that these incarcerations may last only a few days. Finding seven, again generally does not apply as any problems in follow-up are usually the same for the study as a whole.

Clearly, the regulations were written to address research that was conducted in prisons with prisoners as defined population. This was, I believe, the intent of the National Commission in

their 1976 report. The regulations on involving prisoners in research should not generally apply to studies in which individuals become incarcerated subsequent to enrollment in studies intended to be conducted in general populations. Although I think their analysis and conclusion was wrong, if OHRP believes it is not able to return to the prior interpretation because of the way the regulations are worded, then I would strongly suggest that the regulations be revised to make it clear that they apply only to studies conducted in prisons or to studies targeting prison populations and not to studies that may have a subject incidentally incarcerated.

I would like to make a related point. Interpretations by federal agencies that lead to new requirements imparts burden upon IRBs and others in the research enterprise. The research community is willing to undertake additional activities that truly improve human subject safety and welfare, however, adding burden without commensurate benefits to subjects adversely affects the whole system by draining resources and detracts from our important mission.

Interpretations such as this one tend to encourage institutions to limit applicability of their Federal-wide Assurances to federally funded projects only. It also drives research from institutions with FWAs that apply federal regulations to all studies to sites that do not apply the federal regulations. Both of these unintended consequences limit protections available to research subjects.

I ask for wise and cautious exercise of power by our federal regulators and a collaborative process in promulgating new regulations as well as interpreting existing regulations.

Thank you.